

P A T E N T

UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Stewart M. Kume Confirmation No.: 7770
 Serial No.: 09/655,232 Examiner: M. Mendez
 Filing Date: September 5, 2000 Group Art Unit: 3763
 Docket No.: 1001.1726102 Customer No.: 28075
 For: METHODS OF USING AN INTRAVASCULAR BALLOON CATHETER IN
 COMBINATION WITH AN ANGIOSCOPE

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PRE-APPEAL BRIEF REQUEST FOR REVIEWCERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. §1.8 (J)(i)(B))

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Kathleen L. Boekley
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Kathleen L. Boekley
 Signature

May 30, 2006
 Date

Dear Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

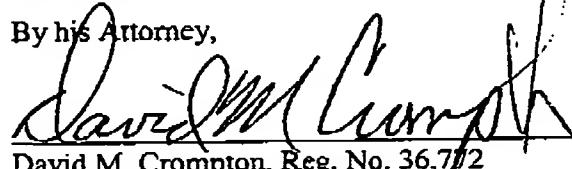
The review is requested for the reasons stated on the attached five sheets of arguments.

This Request is signed by an attorney or agent of record.

Respectfully submitted,

Stewart M. Kume

By his Attorney,


 David M. Crompton, Reg. No. 36,772
 CROMPTON, SEAGER & TUFTE, LLC
 1221 Nicolle Avenue, Suite 800
 Minneapolis, MN 55403-2420
 Telephone: (612) 677-9050

Date: 5/30/06

Attachment: Five Sheets of Pre-Appeal Brief Request Attachment

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PRE-APPEAL BRIEF REQUEST FOR REVIEW ATTACHMENT

CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. §1.8 (1)(B))

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Kathleen L. Boekley May 30, 2006
 Signature Date

Dear Sir:

Appellant has carefully reviewed the Final Office Action dated January 30, 2006 and the Advisory Action dated May 4, 2006. Currently claims 6-9, 13-21 and 24-26 are pending in the application, wherein the Examiner has rejected all pending claims under 35 U.S.C. § 103. Appellant hereby requests a pre-appeal conference and files this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

The Final Office Action failed to make a prima facie case of obviousness and the Advisory Action failed to respond to Appellant's request for reconsideration and instead erroneously denied entry of non-existent amendments.

The claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ishida et al. (U.S. Patent No. 5,002,556) in view of Tanabe et al. (U.S. Patent No. 4,838,879) and Becker et al. (U.S. Patent No. 5,021,043). However, the rejection failed to make a case of prima facie obviousness because it failed to provide a suggestion or motivation to combine the references.

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The Office Action contains two lines of arguments that purport to support an obviousness rejection of independent claims 6 and 18. The first is that Ishida et al. teach "the use of markers in a balloon" and that "it is well established in case law that the mere duplication of a well known element (opaque markers) in an apparatus does not constitute patentable subject matter." The second is that Ishida et al. teach "the use of markers in a balloon" and that Tanabe et al. teach "the use of opaque markers in a catheter arranged in a particular pattern."

As to the first argument, a pattern of opaque markers is more than a mere duplication of an opaque marker. The case where it was held that a mere duplication of a well known element does not constitute patentable subject matter supports this position. The subject matter of the application at issue was water stops placed between adjoining masses of concrete. Concrete shrinks upon curing, leaving gaps which make structures made solely of poured concrete sections impractical for use in dams, swimming pools, reservoirs, etc. One solution is to place a water stop between each pair of sections. The water stop has ribs that extend into each concrete mass and the end result is that any water that passes through the concrete barrier must take a tortuous seepage path. (For a clear description and pictures of this, see U.S. Patent No. 2,228,052 to Gardner.) Claim 1 of the application at issue merely recited a plurality of ribs and the court upheld the rejection. *In re Harza*, 47 C.C.P.A. 771, 774 (C.C.P.A. 1960). It was in regard to this claim that the court wrote the language recited in the MPEP and the Office Action about mere duplication. *Id.* However, the rejection of claim 7 was reversed. Here the court wrote "We refer to the feature of "each rib being substantially as high as the spacing between adjacent ribs." This is novel, and its utility, as expressed by the applicant, is apparent." *Id.* at 775. The other elements of that claim were apparently disclosed in prior art. See *id.* In that claim, however, some relationship between the ribs (even though the ribs themselves were but duplications of a well-known element) was enough to constitute patentable subject matter. Likewise, in the present application, the fact that the opaque markers are in a pattern (and not merely duplicative) constitutes patentable subject matter.

Turning now to the second argument, namely that the claims are obvious in light of Ishida et al. as modified by Tanabe et al., Appellant submits that there is no motivation disclosed in the references to combine them. The Office Action says "modifying the balloon disclosed by Ishida et al., with the multiple markers arranged in a pattern would have been considered obvious because such configuration would have enhanced the capabilities of the catheter system and the

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accuracy of localizing the catheter after deployment to the body." Taking the second motivation first: more markers do not enhance the accuracy of localizing a catheter balloon. Ishida et al. disclose a marker band 24d. As described in Tanabe et al., both the location and angular orientation of the balloon may be known by a single marker band of this sort, whose position is known on the balloon. See column 3, line 31 through column 4, line 16. These two measurements perfectly describe the localization of the balloon. Another marker band will add nothing to this information. Turning now to the first motivation, which is enhancing the capabilities of the catheter system, Appellant is unable to see how Tanabe et al. suggest any enhancements that might be made to Ishida et al. Tanabe et al. mainly discuss what may be done with a single marker band. In only one passage do Tanabe et al. discuss what additional features providing a plurality of ring members may have:

A plurality of radio opaque ring members 3 are preferably formed excluding the one formed in distal end portion 2, as shown in FIG. 2. In this case, if a distance between the adjacent radio opaque ring members is determined, a magnification of the X-ray fluoroscopic image can be known by this distance.

Column 4, lines 21-27. This is undoubtedly true of ring members disposed on a catheter, which does not stretch, but it is just as clearly not true of ring members disposed on the balloon of Ishida et al., which is highly elastic. A comparison of Figures 1 and 3, where the balloon is deflated and inflated respectively, illustrates this vividly. The distance between adjacent ring members can be determined outside the body, but, where those ring members are connected via an elastic and deformable membrane, that distance may change. Consequently, the magnification of the x-ray fluoroscopic image cannot be determined from ring members placed on the balloon of Ishida et al. There is thus no enhancement from having a plurality of ring members taught by Tanabe et al. that would motivate one to modify Ishida et al. to produce a marker system as claimed in the present application. Applicant therefore submits the claims are non-obvious over Ishida et al. alone or in view of Tanabe et al. and are thus in condition for allowance.

Finally, although the Becker et al. patent is cited only in reference to teaching the use of "ink as a marker in the outer wall of a catheter," and thus pertains only to certain dependent claims, Appellant wishes to discuss this patent briefly because it was cited against all the claims. Appellant wishes to make two distinct points in reference to this patent.

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First, that ink has been used on a catheter is not a motivation for putting ink on the balloon of Ishida et al. The Becker et al. catheter is used where the markers are visually perceptible and can be viewed during the process of inflating the balloon. Such ink would be imperceptible in the intravascular balloon process of Ishida et al., where visual means of locating the balloon cannot be used. The balloon of Ishida et al. cannot be viewed from the outside because it is placed inside a patient's body. Nor can the balloon be viewed from the inside because the balloon is filled with a solidifiable liquid, which would prevent angioscopy. See column 5, lines 39-40. Applicant therefore respectfully submits that there is no motivation for modifying Ishida et al. in view of Becker et al.

Second, Becker et al. teach away from the above suggested modification of Ishida et al. in view of Tanabe et al. Becker et al. teach:

The dilatation catheter of the invention has one or more visually perceptible markers having a known spaced relationship from one of the distal end and the proximal end of the center region of an inflatable member. These markers enable alignment of the inflatable member with the obstructed portion of the lacrimal system to be dilated. The arrangement of the markings and the techniques of utilizing the markings varies according to the location of the obstructed portion to be dilated. For treating a failed dacryocystorhinostomy (DCR), for example, a catheter according to the invention includes a first visually perceptible marker spaced 9-13 mm proximal to the proximal end of the center region such that when the catheter is inserted through a punctum and associated canaliculus and then through an ostium formed between the nose and the lacrimal sac, the first marker is aligned relative to the punctum to position the inflatable member. Preferably, the inflatable member is a translucent balloon and a second visually perceptible marker is located beneath the balloon at a distance of 4-6 mm distal to the proximal end of the center region to enable alignment of the second marker relative to the ostium.

Column 3, lines 19-51. Becker et al. are interested in the distance between the ends of the balloon and some markers that are located between the ends of the balloon. Why then do they put the markers on the catheter shaft and make the balloon translucent so the markers can be seen? It would be simpler to put the markers on the balloon where the markers would be visible regardless of the opacity of the balloon—such an arrangement would allow the balloon to be made from more materials. It could be that it simply didn't occur to Becker et al. that one could put a pattern of markers on a balloon, or it could be that Becker et al. didn't think that markers on the balloon would provide a sufficiently accurate distance between those markers and the ends of

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the balloon. Either case supports the proposition that it was not obvious prior to this application to put opaque markers arranged in a pattern on a balloon.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Stewart M. Kume

By his attorney,



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